

NOV 17 2005

*K043367*

**510(K) SUMMARY**

**Date: 19 June 2003**

**Submission Correspondent:** Emergo Group, Inc.

**Address:** 2519 McMullen Booth Road  
Suite 510-295  
Clearwater, Florida 33761

**Phone:** (727) 797-4727

**Fax:** (727) 797-4757

**Contact:** Mr. Rene van de Zande

**Submission Sponsor:** LACE Elettronica s.r.l.

**Trade Name:** GLAID Ocular Electrophysiology Device

**Common Name:** Photostimulator

**Classification:** Ophthalmology

**Description:** The GLAID Ocular Electrophysiology Device generates a display of photic stimuli which the patient observes as a pattern of alternating dark and white bars or checks. The electrical response of the patients' eye is monitored and recorded. The patients' response is measured using electrodes placed on the patients' face and eye

**Intended Use:** The GLAID device is indicated for use in the measurement of visual electrophysiologic potentials, including the electroretinogram (ERG), pattern electroretinogram (PERG), visual evoked potential (VEP) and electrooculogram (EOG), as an aid in the diagnosis and management of Glaucoma when used in conjunction with other established methods of diagnosis and disease management.

**Predicate Devices:** The predicate devices referenced in this submission are: the Electro-Diagnostic Imaging, Inc. VERIS System, the Doran Instruments Inc. Maculoscope, and the LKC Technologies Inc. Electroretinograph.

**Summary and Conclusions Regarding Substantial Equivalence:**

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the GLAID Ocular Electrophysiology Device and the predicate devices cited do not raise any different questions regarding safety and effectiveness. The differences in the technological characteristics are minimal, and the associated procedures are nearly identical. The Intended use is identical to the intended use of the previously cleared predicate devices, and the indications are equivalent.

The device, as designed, is as safe and effective as the predicate devices, and the device is substantially equivalent to the referenced predicate devices.



NOV 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

LACE Elettronica s.r.l.  
c/o Ian P. Gordon  
Emergo Group, Incorporated  
2519 McMullen Booth Road  
Suite 510-295  
Clearwater, FL 33761

Re: K043367

Trade/Device Name: GLAID Ocular Electrophysiology Device  
Regulation Number: 21 CFR 882.1890  
Regulation Name: Evoked Response Photic Stimulator  
Regulatory Class: Class II  
Product Code: GWE  
Dated: October 19, 2005  
Received: October 24, 2005

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first name "David" being the most prominent.

David M. Whipple  
Acting Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

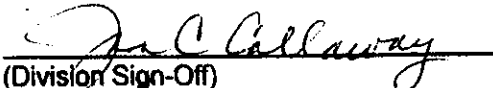
Enclosure

510(k) Number (if known): K 043367

Device Name: GLAID Ocular Electrophysiology Device

**Indications for Use:**

The GLAID device is indicated for use in the measurement of visual electrophysiologic potentials, including the electroretinogram (ERG), pattern electroretinogram (PERG), visual evoked potential (VEP) and electrooculogram (EOG), as an aid in the diagnosis and management of Glaucoma when used in conjunction with other established methods of diagnosis and disease management.

  
(Division Sign-Off)

Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K043367

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

-----  
(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER  
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)